SAFETY DATA SHEETS

This SDS packet was issued with item: 071738608

The safety data sheets (SDS) in this packet apply to one or more components included in the items listed below. Items listed below may require one or more SDS. Please refer to invoice for specific item number(s).

071737402 071737444 071738020 071891258 078289800 078291200 078291900

CONTROLLED COPY

DENTSPLY/International DENTSPLY/Caulk Safety Data Sheet

510897

1. Identification

| 1. Identification | | | |
|--|---|--|--|
| Product Name | SDS Code Number | | |
| IRM [®] LIQUID - Zinc Oxide Eugenol | 510897 | | |
| Intermediate Restorative Material | | | |
| Substance Identity | Date of Last Revision | | |
| IRM [®] LIQUID - Zinc Oxide Eugenol | 04/15/11 | | |
| Intermediate Restorative Material | | | |
| Manufacturer: | Address | | |
| DENTSPLY Caulk | 38 West Clarke Avenue | | |
| | Milford DE 19963-1805 | | |
| | http://www.caulk.com http://www.dentsply.com | | |
| Grades or Minor Variant Identities | Information Telephone Number | | |
| Not Applicable | (302) 422-4511 (8:00 AM – 4:30 PM Eastern Time) | | |
| Product Use (for Canada) | Emergency Telephone Number | | |
| Not Applicable | (302) 422-4511 (8:00 AM – 4:30 PM Eastern Time) | | |

2. Hazard(s) Identification



Warning Causes Skin Irritation

Wash hands thoroughly after handling. Wear protective gloves. IF ON SKIN: Wash with plenty of soap and water. If skin irritation occurs: Get medical advice/ attention. Take off contaminated clothing and wash before reuse.

3. Composition/Information on Ingredients

| Hazardous Components | C.A.S. Number | Exposure Limits | % |
|----------------------|---------------|---------------------|-----------|
| Eugenol | 99-53-0 | 10 mg/M^3 | > than 98 |
| Acetic Acid | 64-19-7 | 10 PPM | < than 2 |

3. Hazard Identification

| Emergency | Emergency Overview: Material may be irritating to eyes. No significant hazards for emergency responses are known. | | | | | | |
|---------------|---|-----------------------------|--------------------------|---------------------------------|-----------------|--|--|
| Routes of | | Single, Repeated, or | Severity (Mild, | Acute and Chronic Health | | | |
| Exposure | Signs and Symptoms | Lifetime Exposure | Moderate, Severe) | Effect(s) | Target Organ(s) | | |
| Eye | Material may cause slight | Single & Repeated | Moderate | Irritation and possible corneal | Not Applicable | | |
| | transient (temporary) irritation. | | | damage due to the powders used | | | |
| | | | | in the product. | | | |
| Skin | Material may be an irritant after | Repeated | Mild | Irritation or possible allergic | Not Applicable | | |
| | repeated and prolonged exposure. | | | response. | | | |
| Inhalation | Not Applicable | Not Applicable | Not Applicable | Not Applicable | Not Applicable | | |
| Ingestion | Material is probably not harmful | Not Applicable | Mild | Not Applicable | Not Applicable | | |
| | if swallowed | | | | | | |
| Other | Not Applicable | Not Applicable | Not Applicable | Not Applicable | Not Applicable | | |
| Medical Con | ditions Aggravated by Exposure Oper | sores and wounds of the | skin. | | | | |
| Carcinogenic | Carcinogenicity NTP?: Not listed IARC monographs?: Not listed OSHA regulated?: No All components of this product are in | | | | | | |
| compliance v | with the inventory listing Requirement | s of the U.S. Toxic Subs | tances Control Act (TSCA |) Chemical Substance Inventory. | | | |
| Potential Env | vironmental Effects Do not allow to er | nter sewers/ surface or gro | ound water. | | | | |

4. First Aid Measures

| Routes of | First Aid Instructions | Immediate Medical | Delayed Effects |
|-----------|---|-------------------|-----------------|
| Exposure | | Attention | |
| Eye | Rinse opened eye for several minutes under running water. | Not Applicable | Not Applicable |
| | If symptoms persist consult a physician. | | |

CONTROLLED COPY

| Skin | Immediately wash with soap and water and rinse thoroughly. | Not Applicable | Not Applicable | | | |
|------------------|--|----------------|----------------|--|--|--|
| Inhalation | Supply fresh air, consult physician if complaint persist. | Not Applicable | Not Applicable | | | |
| Ingestion | Rinse mouth out and then drink plenty of water. | Not Applicable | Not Applicable | | | |
| | Induce vomiting and call for medical help. | | | | | |
| Other | Not Applicable | Not Applicable | Not Applicable | | | |
| Note to Physicia | Note to Physicians (Treating Testing and Monitoring): Treat symptomatically. | | | | | |

5. Fire and Explosion Data

| Flashpoint Method: 110°C (230°F) | Flammable (Explosive) Limits in Air | | Autoignition Temperature: Not | Other: Not | |
|---|--|----------------------|-------------------------------|------------|--|
| Closed Cup | LEL: Not Applicable UEL: Not Applicable | | Applicable. | Applicable | |
| Flame Propagation or Burning Rate (for | Properties Contributing to Fire Intensity: Not | | Flammability Classification: | | |
| Solids) Not Applicable | Applicable | | Not Applicable | | |
| Extinguishing Media: CO ₂ , foam, powder, or water spray. Extinguishing Media to Avoid: Water with full jet. | | | | | |
| Protection and Procedures for Firefighters: Firefighters should wear self-contained respiratory protective devices. | | | | | |
| Unusual Fire and Explosion Hazards: During a fi | re, formation of toxic and/or irritatin | g compounds may be p | present. | | |

6. Accidental Release Measures

Containment Techniques: Absorb spill with inert material (e.g. vermiculite, sand, and earth), then place material in suitable labeled plastic or metal container. Spill/Leak Clean-up Procedures and Equipment: Absorb spill with inert material (e.g. vermiculite, sand, and earth), then place material in suitable labeled plastic or metal container. Ensure adequate ventilation Evacuation Procedures: Not Applicable Special Instructions: Not Applicable Reporting Requirements: Not Applicable

7. Handling and Storage

Handling Practices and Warnings: Product is intended for dental use only. Handling of this product should be by trained dental healthcare professionals only. Observe normal care for working with chemicals

Storage Practices and Warnings: Store only in the original package. Keep package tightly sealed. Store in a dry area. Store away from food and beverages. Protect from heat and direct sunlight.

8. Exposure Control / Personal Protection



| Individual Protection | ividual Protection Personal Protective Equipment for Normal Use | |
|---------------------------|--|--------------------------------------|
| Measures | | Emergencies |
| Eye/Face | Safety Glasses | Not Applicable |
| Skin | The glove material has to be impermeable and resistant to the product. | Not Applicable |
| Inhalation | Not Required | Not Applicable |
| Body Protection | Protective work clothing | Not Applicable |
| Occupational Exposure Lim | its: Not Applicable | Engineering Controls: Not Applicable |

9. Physical and Chemical Characteristics

| Appearance: Colorless or pale yellow liquid. | | Odor: Oil of cloves. |
|--|---|---|
| Normal Physical State: Liquid. | | Melting Point: -10°C (14°F) |
| Specific Gravity: 1.06 g/cm ³ | Solubility in Water: Insoluble | pH: Not Applicable |
| Vapor Pressure (mm Hg): 0.009 | Vapor Density (AIR=1): Not Applicable | Evaporation Rate (Butyl Acetate =1): Not Applicable |
| Flashpoint Method: Not Applicable | Flammable (Explosive) Limits in Air | Autoignition Temperature: Not Applicable |
| | LEL: Not Applicable UEL: Not Applicable | |
| Others Net Applicable | | |

Other: Not Applicable

10. Stability and Reactivity Data

| Incompatibility (Materials to Avoid): Strong oxidizing agents. | | | | |
|--|---------------------------------|--|--|--|
| Hazardous Products Produced During Decomposition: Forms carbon monoxide and/or carbon dioxide. | | | | |
| Hazardous Polymerization: May Occur May Not Occur | Conditions to Avoid: None known | | | |
| Stability? Stable Unstable | Conditions to Avoid: None known | | | |

11.Toxicological Information

Toxicity Data, Epidemiology Studies, Carcinogenicity, Neurological Effects, Genetic Effects, Reproductive Effects, or Structure Activity Data: The Oral LD₅₀ for Eugenol, in rats, is 1930mg/Kg. Emergency Overview: Material may be mildly irritating to eyes. Acute and Chronic Health Routes of Single, Repeated, or Severity (Mild, Signs and Symptoms Torgot Orgon(a) Evnoqura Lifetime Exposure Moderate Severe Effect(s)

| Exposure | Signs and Symptoms | Lifetime Exposure | Moderate, Severe) | Effect(s) | Target Organ(s) |
|----------|-----------------------------------|-------------------|-------------------|-----------------------------------|-----------------|
| Eye | Material may cause slight | Single & Repeated | Moderate | Irritation and possible corneal | Not Applicable |
| | transient (temporary) irritation. | | | damage due to the fillers used in | |
| | | | | the product. | |
| Skin | Material may be an irritant after | Repeated | Mild | Irritation or possible allergic | Not Applicable |
| | repeated and prolonged exposure. | | | response. | |
| | | | | | |

CONTROLLED COPY

| Inhalation | Not Applicable | Not Applicable | Not Applicable | Not Applicable | Not Applicable |
|---|--|----------------|----------------|----------------|----------------|
| Ingestion | Material is probably not harmful | Not Applicable | Mild | Not Applicable | Not Applicable |
| | if swallowed | | | | |
| Other Not Applicable Not Applicable Not Applicable Not Applicable Not A | | | | | Not Applicable |
| Medical Conditions Aggravated by Exposure Open sores and wounds of the skin. | | | | | |
| Carcinogenicity NTP?: Not listed IARC monographs?: Not listed OSHA regulated?: No All components of this product are in | | | | | |
| compliance with the inventory listing Requirements of the U. S. Toxic Substances Control Act (TSCA) Chemical Substance Inventory. | | | | | |
| Potential Environmental Effects: Potential Environmental Effects Do not allow to enter sewers/ surface or ground water. | | | | | |
| NFPA Hazard | NFPA Hazard Classification Ratings (Scale 0-4), Health = 1, Fire = 1, Reactivity = 0 | | | | |

12.Ecological Information

Toxicity Data, Environmental Fate, Physical/Chemical Data, or other Data Supporting Environmental Hazard Statements: Water Hazard Class 1 (Selfassessment): slightly hazardous for water. Do not allow product to reach ground water, water streams or sewage system.

13.Disposal Considerations

Regulations: Must not be disposed of together with household garbage. Dispose of material as solid waste in a closed container. Dispose of in accordance with Federal, State and Local regulations Properties (Physical/Chemical) Affecting Disposal: Dispose of material as solid waste in a closed container.

14.Transport Information

| Regulated for Shipping: No. Not Regulated | DO | T Shipping Name: Not Regulated | Packing Group: Not Applicable |
|--|----|--------------------------------|-------------------------------|
| Do Changes in Quantities, packaging, or shipment | DO | T Hazard Class: Not Applicable | UN Number: Not Applicable |
| method change product classification? No | | | |

15.Regulatory Information

This product has been classified in accordance with the hazard criteria of the Globally Harmonized System of Classification and Labeling of Chemicals and the SDS contains all of the information required by the Canadian Controlled Products Regulations. U.S. Federal Regulations: <u>CERCLA 103 Reportable Quantity</u>: This product is not subject to CERCLA reporting requirements. Many states have more stringent release reporting requirements. Report spills required under federal, state and local regulations

Section 313 Toxic Chemicals: This product contains the following chemicals subject to Annual Release Reporting Requirements Under SARA Title III, Section 313 (40 CFR 372): None

Section 302 Extremely Hazardous Substances (TPQ): None

EPA Toxic Substances Control Act (TSCA) Status: All of the components of this product are listed on the TSCA inventory.

U.S. State Regulations California Proposition 65: This product does not contain any chemicals, which are on the California Proposition 65 list.

Canada WHMIS, Workplace Hazardous Materials Information System: This product is not a controlled product.

International Regulations: Canadian Environmental Protection Act: This product is a medical device and not subject to chemical notification requirements.

European Community Labeling: Not a dangerous preparation.

European Community Labeling: R22 Harmful if swallowed. S24/25 Avoid contact with skin and eyes. S36 Wear suitable protective clothing.

European Inventory of New and Existing Chemicals Substances (EINECS): This product is a medical device and not subject to chemical notification requirements. CAS# Eugenol 97-53-0 EINECS: 202-589-1 Eugenol.

Other: Not Applicable

16.Other Information

To the best of our knowledge this product does not contain gluten, wheat grains, flaxseed, natural rubber, or natural latex. All components are synthetically produced; none are derived from animal products.

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific products features and shall not establish a legally valid contractual relationship.

The attached safety data sheet covers the dangers and measures to be taken when large quantities of material are released, for example due to accidents during transport or storage by the dealer. For quantities of material typically used in clinical practice, information necessary for safe use and storage of the product is given in the DFU.

Safety Data Sheet DentsplySirona

| 1. Identification | |
|---|---|
| Product Name | SDS Code Number |
| IRM [®] LIQUID - Zinc Oxide Eugenol Intermediate | 510897 |
| Restorative Material | |
| Substance Identity | Date of Last Revision |
| IRM [®] LIQUID - Zinc Oxide Eugenol | 7/8/2019 |
| Intermediate Restorative Material | |
| Manufacturer: | Address |
| DENTSPLY Caulk | 38 West Clarke Avenue |
| | Milford DE 19963-1805 |
| | http://www.dentsplysirona.com |
| Grades or Minor Variant Identities | Company Telephone Number (Product Inquiries) |
| Not Applicable | (302) 422-4511 (8:00 AM - 4:30 PM Eastern Time) |
| Product Use (for Canada) | Emergency Telephone Number |
| Not Applicable | CHEMTREC: 1-800-424-9300 (24 hours) |
| | (Outside U.S. +1-703-527-3887) CCN6510 |

2. Hazard(s) Identification



Wash hands thoroughly after handling.

Wear protective gloves. IF ON SKIN: Wash with plenty of soap and water. If skin irritation occurs: Get medical advice/ attention. Take off contaminated clothing and wash before reuse.

3. Composition/Information on Ingredients

| Hazardous Components | C.A.S. Number | Exposure Limits | % |
|----------------------|---------------|------------------------|-----------|
| Eugenol | 97-53-0 | 10 mg/M^3 | > than 98 |
| Acetic Acid | 64-19-7 | 10 PPM | < than 2 |

4. First Aid Measures

| Routes of | First Aid Instructions | Immediate Medical | Delayed Effects |
|------------------|--|-------------------|-----------------|
| Exposure | | Attention | |
| Eye | Rinse opened eye for several minutes under running water. | Not Applicable | Not Applicable |
| | If symptoms persist consult a physician. | | |
| Skin | Immediately wash with soap and water and rinse thoroughly. | Not Applicable | Not Applicable |
| Inhalation | Supply fresh air, consult physician if complaint persist. | Not Applicable | Not Applicable |
| Ingestion | Rinse mouth out and then drink plenty of water. | Not Applicable | Not Applicable |
| | Induce vomiting and call for medical help. | | |
| Other | Not Applicable | Not Applicable | Not Applicable |
| Note to Physici. | ote to Physicians (Treating. Testing and Monitoring): Treat symptomatically. | | |

5. Fire and Explosion Data

Flammable (Explosive) Limits in Air LEL: Not Applicable UEL: Not Applicable Properties Contributing to Fire Intensity: Not Applicable

Flashpoint Method: 110°C (230°F)

Unusual Fire and Explosion Hazards: During a fire, formation of toxic and/or irritating compounds may be present

6. Accidental Release Measures

 Closed Cup
 LEL: Not Appucatio
 ULEL: Not Appucatio

 Flame Propagation or Burning Rate (for
 Properties Contributing to Fire Intensity: Not
 Flam

 Solids) Not Applicable
 Applicable
 Not

 Extinguishing Media: CO₂, foam, powder, or water spray.
 Applicable
 Not

 Protection and Procedures for Firefighters: Firefighters should wear self-contained respiratory protective devices.
 Not

Other: Not Applicable

Air Autoignition Temperature: Not Not Applicable Applicable. ensity: Not Flammability Classification: ensity: Not Not Applicable Extinguishing Media to Avoid: Water with full jet.

| | Other | |
|-----------------------|------------|--|
| Induce vomiti | | |
| Rinse mouth out | Ingestion | |
| Supply fresh air, co | Inhalation | |
| Immediately wash with | Skin | |
| If symptoms | ` | |
| Rinse opened eye for | Eye | |
| | Exposure | |
| | | |

| Containment Techniques: Absorb spill with inert material (e.g. vermiculite, sand, and earth), then place material in suitable labeled plastic or metal container. | | | | | | | |
|---|--------------------------------------|--|--|--|--|--|--|
| Spill/Leak Clean-up Procedures and Equipment: Absorb spill with inert material (e.g. vermiculite, sand, and earth), then place material in suitable labeled | | | | | | | |
| plastic or metal container. Ensure adequate ventilation. | | | | | | | |
| Evacuation Procedures: Not Applicable | Special Instructions: Not Applicable | Reporting Requirements: Not Applicable | | | | | |

7. Handling and Storage

Handling Practices and Warnings: Product is intended for dental use only. Handling of this product should be by trained dental healthcare professionals only. Observe normal care for working with chemicals. Storage Practices and Warnings: Store only in the original package. Keep package tightly sealed. Store in a dry area. Store away from food and beverages.

Protect from heat and direct sunlight.

8. Exposure Control / Personal Protection



| Individual Protection | Personal Protective Equipment for Normal Use | Personal Protective Equipment for | | | | |
|---------------------------|--|-----------------------------------|--|--|--|--|
| Measures | Measures | | | | | |
| Eye/Face | Safety Glasses | Not Applicable | | | | |
| Skin | The glove material has to be impermeable and resistant to the product. | Not Applicable | | | | |
| Inhalation | Not Required | Not Applicable | | | | |
| Body Protection | Protective work clothing | Not Applicable | | | | |
| Occupational Exposure Lim | Engineering Controls: Not Applicable | | | | | |

9. Physical and Chemical Characteristics

| Appearance: Colorless or pale yellow liquid. | | Odor: Oil of cloves. | | | | | | | |
|--|---|---|--|--|--|--|--|--|--|
| Normal Physical State: Liquid. | | Melting Point: -10°C (14°F) | | | | | | | |
| Specific Gravity: 1.06 g/cm ³ | Solubility in Water: Insoluble | pH: Not Applicable | | | | | | | |
| Vapor Pressure (mm Hg): 0.009 | Vapor Density (AIR=1): Not Applicable | Evaporation Rate (Butyl Acetate =1): Not Applicable | | | | | | | |
| Flashpoint Method: Not Applicable | Flammable (Explosive) Limits in Air | Autoignition Temperature: Not Applicable | | | | | | | |
| | LEL: Not Applicable UEL: Not Applicable | | | | | | | | |
| Other: Not Applicable | | | | | | | | | |

10. Stability and Reactivity Data

| Incompatibility (Materials to Avoid): Strong oxidizing agents. | | | | | | | | |
|--|--|--|--|--|--|--|--|--|
| Hazardous Products Produced During Decomposition: Forms carbon monoxide and/or carbon dioxide. | | | | | | | | |
| Hazardous Polymerization: May Occur May Not Occur Conditions to Avoid: None known | | | | | | | | |
| Stability? Stable Unstable Conditions to Avoid: None known | | | | | | | | |

11.Toxicological Information

| Toxicity Data, Epidemiology Studies, Carcinogenicity, Neurological Effects, Genetic Effects, Reproductive Effects, or Structure Activity Data: | | | | | | | | | | |
|---|---|------------------------------|-------------------------|------------------|----------------|--|--|--|--|--|
| The Oral LD ₅₀ for Eugenol, in rats, is 1930mg/Kg. | | | | | | | | | | |
| Emergency Overview: Material may be mildly irritating to eyes. | | | | | | | | | | |
| Routes of Single, Repeated, or Severity (Mild, Acute and Chronic Health | | | | | | | | | | |
| Exposure Signs and Symptoms Lifetime Exposure Moderate, Severe) Effect(s) Target Organ(s) | | | | | | | | | | |
| Eye Material may cause slight transient (temporary) irritation. Single & Repeated Moderate Irritation and possible corneal damage due to the fillers used in the product. Not Applicable | | | | | | | | | | |
| Skin Material may be an irritant after repeated and prolonged exposure. Repeated Mild Irritation or possible allergic response. Not Applicable | | | | | | | | | | |
| Inhalation Not Applicable Not Applicable Not Applicable Not Applicable | | | | | | | | | | |
| Ingestion Material is probably not harmful Not Applicable Mild Not Applicable Not Applicable Not Applicable | | | | | | | | | | |
| Other | Not Applicable | Not Applicable | Not Applicable | Not Applicable | Not Applicable | | | | | |
| Medical Conditions Aggravated by Exposure Open sores and wounds of the skin. | | | | | | | | | | |
| Carcinogenicity NTP?: Not listed IARC monographs?: Not listed OSHA regulated?: No All components of this product are in | | | | | | | | | | |
| compliance with the inventory listing Requirements of the U. S. Toxic Substances Control Act (TSCA) Chemical Substance Inventory. | | | | | | | | | | |
| Potential Envir | onmental Effects: Potential Environme | ental Effects Do not allow t | o enter sewers/ surface | or ground water. | | | | | | |
| NFPA Hazard (| Classification Ratings (Scale 0-4), Hea | lth = 1, Fire = 1, Reactivit | y = 0 | | | | | | | |

12.Ecological Information

Toxicity Data, Environmental Fate, Physical/Chemical Data, or other Data Supporting Environmental Hazard Statements: Water Hazard Class 1 (Selfassessment): slightly hazardous for water. Do not allow product to reach ground water, water streams or sewage system.

13.Disposal Considerations

Regulations: Must not be disposed of together with household garbage. Dispose of material as solid waste in a closed container. Dispose of in accordance with Federal, State and Local regulations

| Prop | erties | (Ph | vsical/ | Che | mica | 1) A | Affect | ting | Dis | posal | : Dis | pose | of | material | as | solid | was | te in | a c | losed | contai | ner. |
|------|--------|-----|---------|-----|------|------|--------|------|-----|-------|-------|------|----|----------|----|-------|-----|-------|-----|-------|--------|------|
| | | | | | | | | | | | | | | | | | | | | | | |

14.Transport Information

| Regulated for Shipping: No. Not Regulated | DOT Shipping Name: Not Regulated | Packing Group: Not Applicable |
|--|----------------------------------|-------------------------------|
| Do Changes in Quantities, packaging, or shipment | DOT Hazard Class: Not Applicable | UN Number: Not Applicable |
| method change product classification? No | | |

15.Regulatory Information

| This product has been classified in accordance with the hazard criteria of the Globally Harmonized System of Classification and |
|---|
| Labeling of Chemicals and the SDS contains all of the information required by the Canadian Controlled Products Regulations. |
| U.S. Federal Regulations: <u>CERCLA 103 Reportable Quantity</u> : This product is not subject to CERCLA reporting requirements. |
| Many states have more stringent release reporting requirements. Report spills required under federal, state and local |
| regulations |
| Section 313 Toxic Chemicals: This product contains the following chemicals subject to Annual Release Reporting |
| Requirements Under SARA Title III, Section 313 (40 CFR 372): None |
| Section 302 Extremely Hazardous Substances (TPQ): None |
| EPA Toxic Substances Control Act (TSCA) Status: All of the components of this product are listed on the TSCA inventory. |
| U.S. State Regulations California Proposition 65: This product does not contain any chemicals, which are on the California |
| Proposition 65 list. |
| Canada WHMIS, Workplace Hazardous Materials Information System: This product is not a controlled product. |
| International Regulations: Canadian Environmental Protection Act: This product is a medical device and not subject to |
| chemical notification requirements. |
| European Community Labeling: Not a dangerous preparation. |
| European Community Labeling: R22 Harmful if swallowed S24/25 Avoid contact with skin and eyes S36 Wear suitable protective clothing |

European Community Labeling: R22 Harmful if swallowed. S24/25 Avoid contact with skin and eyes. S36 Wear suitable protective clothing. European Inventory of New and Existing Chemicals Substances (EINECS): This product is a medical device and not subject to chemical notification requirements. CAS# Eugenol 97-53-0 EINECS: 202-589-1 Eugenol.

Other: Not Applicable

16.Other Information

To the best of our knowledge this product does not contain gluten, wheat grains, flaxseed, natural rubber, or natural latex. All components are synthetically produced; none are derived from animal products.

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific products

features and shall not establish a legally valid contractual relationship.

The attached safety data sheet covers the dangers and measures to be taken when large quantities of material are released, for example due to accidents during transport or storage by the dealer. For quantities of material typically used in clinical practice, information necessary for safe use and storage of the product is given in the DFU.